NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SHAMIK VAKIL, *Plaintiff,* v. BAYER HEALTHCARE, LLC, BAYER CORPORATION, and BAYER HEALTHCARE PHARMACEUTICALS, INC., *Defendants.*	Civil Action No. 13-00080 **OPINION**

John Michael Vazquez, U.S.D.J.

I. INTRODUCTION

This matter comes before the Court on Defendants Bayer Healthcare, LLC, Bayer Corporation, and Bayer Healthcare Pharmaceuticals, Inc.'s (collectively "Bayer" or "Defendants") motion for summary judgment. The Court considered the written submissions of the parties and heard oral argument. For the reasons that follow, Bayer's motion is granted.

II. FACTS AND PROCEDURAL HISTORY

The facts of this matter are derived largely from the parties' pleadings, deposition testimony, and other evidence developed during discovery. The facts are presented in the light most favorable to the non-moving party, Plaintiff. *See Tolan v. Cotton*, 134 S. Ct. 1861, 1866 (2014) (noting that in motion for summary judgment, "a court must view the evidence in the light most favorable to the opposing party" (internal quotation marks omitted)).

Avelox is a prescription antibiotic, approved by the Food and Drug Administration ("FDA"), that has been manufactured by Bayer since 1999. Leskin Cert.[1] at ¶ 7 (D.E. 70-1). Avelox is in a class of antibiotics referred to as fluoroquinolones and is prescribed to treat certain bacterial infections in adults who are 18 years or older. *Id.*, Ex. 5 at 1.

Plaintiff Dr. Shamik Vakil is a pediatric dentist who, on or around October 25, 2011, was prescribed a six-day course of Avelox by his family physician, Dr. Roland Bercasio, to treat Plaintiff's severe bronchitis. Complaint ("Compl.") at ¶ 18. Dr. Bercasio provided Plaintiff with six sample doses of Avelox, as a result, Plaintiff did not need to fill a prescription at a pharmacy. Milstein Cert.,[2] Ex. F, Plaintiff's Deposition ("Pl. Dep.") at 100:24 to 101:4; 102:12-24. Plaintiff testified that Dr. Bercasio told him that Avelox would help him get better, but that Dr. Bercasio did not inform him of the risks associated with Avelox. *Id.* at 103:1-14; 115:16 to 116:11.

On October 30, 2011, after taking five out of six doses of Avelox, Plaintiff alleges that he "experienced an adverse reaction to the drug, which resulted in symptoms so severe that [he] was no longer able to work, and had to move to his parents' house." Compl. ¶¶ 19-22. Plaintiff did not take the sixth and final dose of Avelox. *Id.* at ¶ 20.

Plaintiff testified that after taking Avelox his "entire life fell apart." Pl. Dep. at 52:6. Plaintiff explained that his hands would shake so much that he could not hold a spoon when eating a bowl of cereal without the milk spilling out. *Id.* at 130:10-14. Without steady hands, Plaintiff could not perform his job as a dentist. *Id.* at 130:15-19. According to Plaintiff, some of his other symptoms included, but were not limited to, experiencing (1) a high pitched ring in his ears, (2)

[1] Leskin Cert. refers to the Certification of Lori B. Leskin and the exhibits attached thereto. D.E. 70.

[2] "Milstein Cert." refers to the Certification of Alan C. Milstein and the exhibits attached thereto. D.E. 74

involuntary spasms in parts of his body, (3) insomnia caused by shaking so severe that "it felt like a seizure" as well as waking up during the night due to shaking, (4) pain in his hands, feet, ankles, and knees, (5) numbness in his hands, (6) confusion when completing simple tasks, (7) digestive difficulty and diarrhea, and (8) nausea as if he was "hungover" from drinking, even though he had not consumed alcohol, when he awoke. *Id.* at 134:4 to 144:4.

After having seen over twenty physicians in various specialties (Milstein Cert. Ex. E at interrogatory 9), in September 2012, Plaintiff was examined by Dr. Murray R. Berkowitz, (*id.* Ex. C at 1 ("Berk. Report")). On November 4, 2013, Dr. Berkowitz issued an expert report explaining that Plaintiff had "multiple medical problems that significantly impact[ed] his activities and daily living." Berk. Report at 2. Dr. Berkowitz concluded that Plaintiff's primary medical conditions were "constant pain and neuromusculoskeletal symptoms, especially the tremors in his upper extremities." *Id.* After reviewing Plaintiff's medical records, reports, and examinations, Dr, Berkowitz also determined that Plaintiff was suffering from twenty-eight medical conditions. *Id.* at 3-4. Those conditions were: dysautonomia, quinolone toxicity, medication side effects, cervical radiculitis, thoracic radiculitis, cervicalgia, thoracic spine pain, muscle spasm, cranial somatic dysfunction, cervical spine somatic dysfunction, thoracic spine somatic dysfunction, lower extremity somatic dysfunction, tinnitus, paresthesias/numbness, tremor, abnormal involuntary movements, EEG abnormalities, generalized anxiety disorder, mood disorder, insomnia, sleep disturbances, memory problems, ataxia, fatigue, visual loss, shortness of breath/dyspnea, bradycardia, and cephalalgia. *Id.* In a supplemental expert report, Dr. Berkowitz further diagnosed Plaintiff with hip/pelvis somatic dysfunction and sacral somatic dysfunction. Leskin Cert., Ex. 2

at 2. All of Plaintiff's symptoms appear on the Avelox warning label or are encompassed by a similar or broader warning of a related ailment included on the label.[3]

Toward the end of 2013, after experiencing little to no relief from his symptoms, Plaintiff traveled to India with his father to seek alternative forms of treatment. Pl. Dep. 188:3 to 191:2; 195:9-10. Plaintiff was treated by an acupuncturist as well as a person "skilled in naturopathic and ayurvedic medicine."[4] *Id.* at 190:19 to 191:2. After receiving treatment and returning to the United States, Plaintiff's symptoms were "substantially resolved." *Id.* at 195:6-10.

On January 3, 2013, Plaintiff filed a five-count complaint against Defendants. Plaintiff alleged causes of action for (1) strict liability, (2) breach of express warranty, (3) breach of implied warranty, (4) negligence, and (5) negligent misrepresentation. Compl. ¶¶ 29-58. On April 15, 2016, after the close of discovery, Defendants filed a motion for summary judgment. D.E. 69 & 70.[5] Thereafter, Plaintiff filed an opposition, and Defendants filed a reply. On December 1, 2016, the Court heard oral argument.

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[3] Despite the fact that some of Plaintiff's thirty diagnosed symptoms do not appear verbatim on the Avelox label, Plaintiff has not argued that the warning label is deficient for failing to include any of the symptoms he suffered. At oral argument, Defendants contended, and Plaintiff did not dispute, that Plaintiff's symptoms which do not appear word-for-word on the warning label, such as "medicinal side effects," are part of a catch-all diagnosis that is encompassed by the other warnings on the Avelox label. Plaintiff also did not take a contrary position in his briefing. In fact, Plaintiff's expert Dr. Berkowitz indicated that all of Plaintiff's symptoms were listed or "consistent with" those on the warning label. Berk. Report at 4. Accordingly, the parties do not contest that all of Plaintiff's diagnosed symptoms are covered by the Avelox label.

[4] Plaintiff explained that naturopathic and ayurvedic medicine uses herbs, spices, and sometimes a particular diet as a form of treatment. Pl. Dep. 191:3 to 192:6.

[5] Defendants' brief and supporting papers in support of their motion for summary judgment will be referred to as "Def. Br." Plaintiff's submissions in opposition (D.E. 74) will be called "Pl. Br." Defendants' reply papers (D.E. 77) will be referred to as "Def. Rep."

Defendants first argue that summary judgment is proper because "[u]nder Virginia law, plaintiffs asserting a products liability claim are limited to theories of negligence and breach of implied warranty of merchantability" and that "[n]o other causes of action are permitted."[6] Def. Br. at 10-11. Accordingly, Defendants maintain that Plaintiff's claims for strict liability, breach of express warranty, and negligent misrepresentation should be dismissed. *Id.* at 11.

Second, Defendants contend that the remaining two counts -- negligence and breach of implied warranty -- are barred by the learned intermediary doctrine. *Id.* at 13. Defendants note that the only potentially viable theory set forth by Plaintiff supporting those claims is Defendants' alleged failure to warn of Avelox's harmful effects. *Id.* at 12. Defendants posit that each of Plaintiff's alleged injuries is identified in the information provided on the Avelox warning label, and thus, Plaintiff failed to meet his burden in proving his failure to warn claim. *Id.* at 13-14.

Plaintiff counters that the learned intermediary doctrine does not shield Defendants from liability because the Avelox label did not provide adequate warnings to the prescribing physicians. Pl. Br. at 9. Plaintiff argues that "Bayer's reliance on the learned intermediary doctrine fails as the prescribing information did not warn of the risk of permanent peripheral neuropathy at the time Dr. Bercasio prescribed the drug." *Id.* at 10. Moreover, Plaintiff points out that Dr. Bercasio testified that he read the Avelox label "[m]any years" prior to prescribing it, but even if he had read the label "prior to prescribing Avelox to Plaintiff, Dr. Bercasio could not have informed him of the risk of permanent peripheral neuropathy as that condition was not disclosed as a risk by Bayer until almost two years later." *Id.* In short, Plaintiff maintains that Defendants did not

[6] Both parties agree that Virginia law governs the substantive claims of this dispute. According to Defendants' brief, Plaintiff was prescribed Avelox by a Virginia doctor and took the drug while living in Virginia. Def. Br. at 11 n.2 (citing *Atkinson v. Forest Research Inst., Inc.*, No. 13-1832, 2014 WL 2773657, at *4 (D.N.J. June 18, 2014) (applying Indiana law when plaintiff and decedent resided, were prescribed, and ingested allegedly harmful drug in Indiana)).

adequately communicate the risks of Avelox to Dr. Bercasio, and thus, he could not properly inform Plaintiff of those risks. *Id.* at 10-11.

Defendants respond that the presence, or lack thereof, of a peripheral neuropathy warning on the Avelox label is irrelevant because "no physician has ever diagnosed [Plaintiff] with peripheral neuropathy." Def. Rep. at 2 (emphasis omitted). Defendants contend that they cannot be liable for failing to warn of a condition that was not actually suffered by Plaintiff. *Id.* at 2-3. Nonetheless, according to Defendants, the warning on the label was sufficient because it contained adequate information about the risks of peripheral neuropathy in three different sections. *Id.* at 3-4. Finally, Defendants argue that it is of no legal consequence whether Dr. Bercasio reviewed Avelox's warning label prior to prescribing it to Plaintiff. *Id.* at 4. Defendants maintain that "once a manufacturer has satisfied its obligation to warn via product labeling, it is legally irrelevant if the doctor actually reviewed the label or whether he chose to pass that information on to his patient."[7] *Id*

III. LAW AND ANALYSIS

Standard of Review

A moving party is entitled to summary judgment where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is "material" when a dispute over that fact "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Importantly, "[f]actual disputes that are irrelevant or unnecessary will not be counted." *Id.* A

[7] Defendants also moved for summary judgment arguing that Plaintiff's expert's testimony is inadmissible pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 582 (1993), and thus, Plaintiff cannot prove the essential element of causation. Because the Court finds that Defendants are entitled to summary judgment in light of the alleged causes of actions and facts, the Court does not reach the *Daubert* argument.

material fact raises a "genuine" dispute "if the evidence is such that a reasonable jury could return a verdict for the non-moving party." *Williams v. Borough of W. Chester*, 891 F.2d 458, 459 (3d Cir. 1989). "Where the record taken as a whole could not lead a reasonable trier of fact to find for the non-moving party, there is no genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (internal quotation marks omitted). "When analyzing the sufficiency of the evidence, the court must view the facts and any reasonable inferences drawn therefrom in the light most favorable to the party opposing summary judgment." *InterVest, Inc. v. Bloomberg, L.P.*, 340 F.3d 144, 159-60 (3d Cir. 2003).

Summary judgment is appropriate "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Under those circumstances, "there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Id.* at 322-23. However, to withstand a motion for summary judgment, the nonmoving party need only "come forward with evidence which, if believed, would support a finding in its favor." *In re Bressman*, 327 F.3d 229, 237 (3d Cir. 2003).

Strict Liability, Negligent Misrepresentation, and Breach of Express Warranty

Defendants argue that under Virginia law, Plaintiff may not assert claims of strict liability, negligent misrepresentation, and breach of express warranty when proceeding under a theory of products liability. Plaintiff does not respond to these arguments in his opposition brief. However, at oral argument, Plaintiff's counsel conceded that he did not have any authority contradicting Defendants' position as to strict liability and negligent misrepresentation.

As to strict liability, the Court concludes that Plaintiff's claim fails because "Virginia law . . . does not permit tort recovery on a strict-liability theory in products-liability cases." *Sensenbrenner v. Rust, Orling & Neale, Architects, Inc.*, 374 S.E. 2d 55, 57 n.4 (Va. 1988); *see also Belcher v. J.H. Fletcher & Co.*, No. 93–2424, 1995 WL 300030, at *1 (4th Cir. May 18, 1995) (affirming district court's dismissal of strict liability claim because "Virginia law does not recognize strict liability in products liability actions"); *Sanyal v. Toyota Motor N. Am., Inc.*, No. 14-960, 2015 WL 236649, at *2 (E.D. Va. Jan. 15, 2015) ("Virginia does not permit tort recovery on a strict-liability theory in products liability cases."); *Sykes v. Bayer Pharm. Corp.*, 548 F. Supp. 2d 208, 214 (E.D. Va. 2008) ("[C]ourts applying Virginia law have not applied the doctrine of strict liability in product liability cases."); *St. Jarre v. Heidelberger Druckmaschinen A.G.*, 816 F. Supp. 424, 427 (E.D. Va. 1993) (stating that "it is beyond question that Virginia does not recognize a cause of action for strict liability in tort"), *aff'd*, 19 F.3d 1430 (4th Cir. 1994); *Providence Vill. Townhouse Condo. Ass'n v. Amurcon-Loudoun Corp.*, 33 Va. Cir. 165, 168 (Cir. Ct. 1994) ("Virginia does not recognize strict liability as a ground for recovery in products liability cases."). Accordingly, summary judgment is granted to Defendants as to Plaintiff's claim for strict liability.

Similarly, Plaintiff's claim for negligent misrepresentation fails because "Virginia does not recognize any tort of negligent misrepresentation." *Bentley v. Legent Corp.*, 849 F. Supp. 429, 434 (E.D. Va. 1994), *aff'd sub nom. Herman v. Legent Corp.*, 50 F.3d 6 (4th Cir. 1995); *see also Lescs v. William R. Hughes, Inc.*, 168 F.3d 482 (4th Cir. 1999) ("[T]he federal courts of this Circuit repeatedly have determined that Virginia does not recognize a general cause of action for negligent misrepresentation."); *Baker v. Elam*, 883 F. Supp. 2d. 576, 581 (E.D. Va. 2012) ("Virginia courts . . . do not recognize negligent misrepresentation as a separate cause of action from that of constructive fraud."); *Lesner Pointe Condo. Ass'n v. Harbour Point Bldg. Corp.*, 61 Va. Cir. 609,

615 (Cir. Ct. 2002) (declining "to recognize negligent misrepresentation as a distinct cause of action"); *Bay Point Condo. Ass'n, Inc. v. RML Corp.*, 52 Va. Cir. 432, 443 (Cir. Ct. 2000) ("The Virginia Supreme Court has not . . . recognized a separate and independent cause of action for negligent misrepresentation[.]"). Therefore, summary judgment is granted to Defendants as to Plaintiff's claim for negligent misrepresentation.

Next, Defendants contend that Plaintiff may not assert a claim for breach of express warranty in conjunction with his products liability claim. Def. Br. at 10-11 (arguing that "plaintiffs asserting a products liability claim are limited to theories of negligence and breach of implied warranty of merchantability"). Defendants cite to *Talley v. Danek Med., Inc.*, 179 F.3d 154, 163-64 (4th Cir. 1999) to support that proposition. Def. Br. at 11. In *Talley*, the Fourth Circuit affirmed the grant of summary judgment as to the plaintiff's breach of express warranty claim finding that it was precluded by the learned intermediary doctrine. 179 F.3d at 163-64. Contrary to Defendants' contention, however, the court did not hold that a claim for breach of express warranty was prohibited in a products liability case. *Id.* To the contrary, by analyzing whether the breach of express warranty claim was precluded by the learned intermediary doctrine, the Fourth Circuit implicitly recognized that the warranty claim was not barred as a matter of law. *See id.*; *see also Young v. J. I. Case Co.*, No. 90-00630, 1994 WL 506403, at *2-3 (E.D. Va. June 3, 1991) (conducting substantive analysis on claim for breach of express warranty in products liability action).[8]

[8] Defendants also cite to *Bly v. Otis Elevator Co.*, 713 F.2d 1040, 1042 (4th Cir. 1983) to support its argument that "plaintiffs asserting a products liability claim are limited to theories of negligence and breach of implied warranty of merchantability" and that "[n]o other causes of action are permitted." Def. Br. at 10-11. The Fourth Circuit in *Bly* stated that "manufacturers and sellers of defective products *can* be held liable on theories of negligence and breach of the implied warranty of merchantability." 713 F.2d at 1042 (emphasis added). Importantly, however, the court did not rule that a plaintiff may not claim breach of express warranty as an independent cause of action.

The Court concludes that Virginia law does not preclude Plaintiff from asserting a claim for breach of express warranty in a products liability action. Defendants have cited no legal authority, and the Court has found none, explicitly barring such a claim simply because a plaintiff has also asserted a products liability claim. With that being said, however, Plaintiff has not established the essential elements of a claim for breach of express warranty.

In Virginia, "[a]n express warranty is any affirmation concerning the character, quality or condition of goods, having the effect of inducing a sale, if the buyer purchases the goods relying thereon." *Carney v. Sears, Roebuck & Co.*, 309 F.2d 300, 303 (4th Cir. 1962); *see also* Va Code Ann. § 8.2-313. In this case, neither Plaintiff's opposition brief nor his statement of undisputed material facts identifies the alleged affirmation that created an express warranty or how that warranty was allegedly breached. The only evidence supporting Plaintiff's express warranty claim is found in his complaint, which states that "Defendants expressly warranted to physicians and consumers, including [P]laintiff and/or his physicians, that Avelox was safe and/or well tolerated." Compl. at ¶ 37. Plaintiff alleges that "Avelox does not confirm to these express representations because it is not safe and/or well-tolerated because it causes serious adverse effects and harm, such as those experienced by [P]laintiff." Id. at ¶ 38. Plaintiff has pointed to no evidence in the record to support those allegations. Importantly, during oral argument, Plaintiff could not point to any alleged affirmation when questioned by the Court, and instead indicated that his theory was more akin to an omission. Therefore, summary judgment is granted to Defendants as to the breach of express warranty claim.

The Learned Intermediary Doctrine

The next issue is whether the learned intermediary doctrine bars Plaintiff's claims for breach of the implied warranty of merchantability and negligence.

In Virginia, "manufacturers and sellers of defective products can be held liable on theories of negligence and breach of the implied warranty of merchantability." *Bly v. Otis Elevator Co.*, 713 F.2d 1040, 1042 (4th Cir.1983). In practice, the two different theories are essentially treated the same in law. "The elements of both a negligence and a warranty cause of action are largely identical." *Higgins v. Forest Labs.*, 48 F. Supp. 3d 878, 883 (W.D. Va. 2014). Under either theory, "the plaintiff must show, (1) that the goods were unreasonably dangerous either for the use to which they would ordinarily be put or for some other reasonably foreseeable purpose, and (2) that the unreasonably dangerous condition existed when the goods left the defendant's hands." *Id.* at 884. "'Unreasonably dangerous' products are those: (i) defective in assembly or manufacture; (ii) imprudently designed; or (iii) not accompanied by adequate warnings about their hazardous properties." *Butler v. Navistar Int'l Transp. Corp.*, 809 F. Supp. 1202, 1206 (W.D. Va. 1991). Here, Plaintiff is proceeding under the third theory, that is, Defendants did not provide adequate warnings about Avelox's properties. *See* Pl. Br. at 9-11. Defendants counter that the warnings on the Avelox label were adequate, and as a result, they are shielded from liability by the learned intermediary doctrine. Def. Br. at 10-14.

The learned intermediary doctrine provides an exception to the general rule that "a manufacturer has a duty to warn its customers of risks posed by its products." *Higgins*, 48 F. Supp. 3d at 884. "The learned intermediary doctrine provides that manufacturers of prescription drugs and medical devices discharge their duty of care to patients by providing adequate warnings to the prescribing physicians." *Id.* (internal quotation marks omitted). In other words, "the manufacturer's duty to warn extends only to the prescribing physician, who then assumes responsibility for advising the individual patient of risks associated with the drug or device." *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992); *see also Talley*, 179 F.3d at 163

(explaining that where medication can only be prescribed by a physician and the physician does so after having evaluated the patient, "the manufacturer of the drug . . . owes the patient only the duty to warn the physician and to provide the physician with adequate product instructions"); *Abbot by Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, (4th Cir. 1988) ("With prescription drugs, the duty is not the normal duty to warn the ultimate consumer. Rather, the duty is to warn the physician administering the drug."). The rationale for the learned intermediary doctrine has been described by the Fourth Circuit as follows:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.
>
> [*Stanback v. Parke, Davis & Co.*, 657 F.2d 642, 644 (4th Cir. 1981) (internal quotation marks omitted).]

Often, "[t]he adequacy of a warning is a question of fact for the jury." *Abbot*, 844 F.2d at 1115. However, "[c]ourts have routinely held warnings adequate as a matter of law when they alert a party to the very injury for which the plaintiff seeks relief." *Ball v. Takeda Pharm. Am., Inc.*, 963 F. Supp. 2d 497, 504 (E.D. Va. 2013), *aff'd*, 587 F. App'x 78 (4th Cir. 2014); *see also Kling v. Key Pharm., Inc.*, 35 F.3d 556 (4th Cir. 1994) ("The precise harm alleged to be suffered by [the plaintiff], a seizure, was clearly listed as a potential side effect of taking [the prescription drug in question].")

Here, the learned intermediary doctrine bars Plaintiff's claims for negligence and breach of the implied warranty of merchantability. The Avelox label contained adequate warnings for all of the symptoms with which Dr. Bercasio diagnosed Plaintiff. Dr. Berkowitz's November 4, 2013 expert report acknowledges that Plaintiff's symptoms were included on Avelox's warning label. Berk Report at 3-5. By providing warnings to Plaintiff's physician of the exact harm eventually suffered by Plaintiff, Defendants discharged their duty owed to Plaintiff and are protected from liability pursuant to the learned intermediary doctrine. *See Ball*, 963 F. Supp. 2d at 504.

Plaintiff argues that the learned intermediary doctrine is inapplicable because the Avelox label did not warn of the risk of permanent peripheral neuropathy when Dr. Bercasio prescribed the drug. Plaintiff notes that sometime after Plaintiff took Avelox, the FDA required Bayer to include permanent peripheral neuropathy in its "black box warning." Plaintiff, however, was never diagnosed with permanent peripheral neuropathy. Berk. Dep. 207:3 to 208:10; 224:10-16. Defendants cannot be held accountable for failing to warn Plaintiff of a symptom he never experienced. *See Novak v. United States*, 865 F.2d 718, 726 (6th Cir. 1989) (concluding that "district court erred in finding the warning inadequate, negligent, and insufficient because it did not specifically caution those who may have experienced 'viral encephalitis'" when there was no evidence that plaintiff "had actually suffered from viral encephalitis"); *Mills v. United States*, 764 F.2d 373, 379 (5th Cir. 1985) ("The question of the adequacy of the warnings must be confined to consideration of whether the warnings were sufficient to inform the plaintiff of the risk of the particular condition or disease which allegedly caused his injury or death."); *Tyree v. Boston Sci. Corp.*, No. 12-08633, 2014 WL 5445769, at *6 (S.D.W. Va. Oct. 22, 2014) (explaining that in failure to warn claims "only the injuries experienced by the complainant are relevant").

Furthermore, Plaintiff's claim that Defendants did not warn physicians of the risk of peripheral neuropathy is belied by the Avelox warning label itself. At the time Plaintiff was prescribed Avelox, its warning label included information about the risk of peripheral neuropathy in the Warnings and Precautions section, in the Serious and Potentially Serious Adverse Reactions section, and in the Patient Medication Guide.[9] Leskin Cert., Ex. 5 at 6, 28-29, 32-33. Therefore, the Court finds that Plaintiff's argument is without merit.

Plaintiff also contends that the learned intermediary doctrine is inapplicable because Dr. Bercasio read the Avelox label "[m]any years ago" and did not inform Plaintiff of its risks. Pl. Br. at 10. Plaintiff's argument misconstrues the learned intermediary doctrine. The very purpose of the doctrine is to pass the duty to inform a patient of a drug's risks to the patient's doctor because he or she is in the best position to evaluate those risks and explain them to the patient. *Stanback*, 657 F.2d at 644. The manufacturer satisfies its duty once it informs the physician of those risks. *Id.* The fact that Dr. Bercasio had not read Avelox's label in a number of years and did not explain its risks to Plaintiff is irrelevant as to the question of whether Defendants satisfied their duty to warn Dr. Bercasio in the first instance.

Additionally, Plaintiff claims that "the sample packs provided to Dr. Bercasio, and consequently to Plaintiff, may not have contained [Avelox's] package inserts." Pl. Br. at 10. It appears that Plaintiff is claiming that if the Avelox samples did not include the package inserts,

[9] Although it is not entirely clear from Plaintiff's brief, it appears that Plaintiff is arguing that the Avelox label included information solely about peripheral neuropathy (as opposed to *permanent* peripheral neuropathy, which Plaintiff alleges was added to the label around 2013 (Pl. Br. at 10)). Assuming that is Plaintiff's contention, the Court nonetheless rejects it because the label during the relevant period explicitly stated that "Avelox may need to be stopped to prevent *permanent* nerve damage." Leskin Cert. Ex. 5 at 33 (emphasis added). According to the Avelox label, peripheral neuropathy is "[d]amage to the nerves in arms, hands, legs, or feet." *Id.* More importantly, and as noted, Plaintiff was never diagnosed with either peripheral neuropathy or permanent peripheral neuropathy.

Defendants failed to satisfy their duty to warn Dr. Bercasio of Avelox's risks. Assuming for purposes of argument that Plaintiff asserts a viable legal theory, Plaintiff has not presented any competent evidence to support his claim that the package inserts were not included in the sample boxes of Avelox. When asked in his deposition whether the Avelox sample boxes contained a package insert, Plaintiff responded "I don't recall. I haven't seen it in quite a while." Pl. Dep. 216:20 to 217:4. That evidence falls below the burden a plaintiff must meet to establish a genuine issue of material fact during the summary judgment stage. *See Good v. Dauphin Cty. Soc. Servs. for Children & Youth*, 891 F.2d 1087, 1096-97 (3d Cir. 1989) (noting that plaintiff has the burden to present competent evidence in order to overcome motion for summary judgment); *see also Barnette v. E.R. Squibb & Sons, Inc.*, 670 F.Supp. 650, 651 (E.D.Va.1987) (granting judgment as a matter of law where both the Physician's Desk Reference and package inserts carried warnings that the harm plaintiff suffered was a possible side effect associated with the use of the drug, even where the plaintiff argued, but failed to show, that the physician may not have received the package insert). In short, Plaintiff's evidence is merely speculation as to what might, or might not, have actually occurred.

Accordingly, Plaintiff has failed to meet his burden as to his claims for negligence and breach of the implied warranty of merchantability. Summary judgment is granted to Defendants as to both counts.[10]

IV. CONCLUSION

[10] Although Defendants' motion for summary judgment as to the breach of express warranty claim has already been granted, the Court notes that the express warranty claim also fails under the learned intermediary doctrine. Accordingly, the learned intermediary doctrine likewise precludes Plaintiff's claim for breach of express warranty.

For the reasons set forth above, Defendants' motion for summary judgment is granted. An appropriate order will be entered on the docket.

Dated: December 7, 2016

John Michael Vazquez, U.S.D.J.